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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,747	01/24/2002	Hideharu Chono	MUR-032-USA-PCT	8613

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/031,747

Applicant(s)

CHONO ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment and Response dated 4/15/03.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 11-15, and 20-26 rejected under 35 U.S.C. 102(b) as being anticipated by

Higo et al (WO 96/16642) [*Note: all citations refer to the English equivalent USPN 5,866,157*].

The claims are drawn to a matrix-type transdermal patch formulation comprising a basic drug, an organic acid, and an organic acid salt. The composition is water free. The basic drug is selected from a wide range of possible classes.

Higo et al discloses a matrix patch formulation that is free of water (Abstract). The formulation comprises a basic drug (col. 3, lin. 23 – 53), organic acids and their salts (col. 2, lin. 55 – col. 3, lin. 11). Sodium acetate is named as one of the many organic acid salts useful in the invention of Higo. Basic drugs include skeletal muscle relaxants such as pridinol mesilate or antiemetic agents such as betahistine. These disclosures along with others render the claims of the invention anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 7-10 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higo et al (WO 96/16642) in view of Chono et al (WO 97/42952) [*Note: all citations will refer to the English language equivalents USPN 5,866,157 and USPN 6,139,866*]. The claims are drawn to a matrix-type transdermal patch comprising specific concentrations and ratios of a basic drug, and organic acid and an organic acid salt. The formulation is free of water.

As discussed above Higo discloses a matrix formulation comprising a basic drug, organic acids and their salts. The reference however does not disclose the specific concentrations and ratios of the components of the matrix. The reference however does disclose the concentrations of the organic acid and the basic drug (0.1% to 20 % and 15% to 60% respectively). These concentrations are within the levels of those of the invention. Also it would be within the levels of skill in the art to substitute the concentration of the organic acid to that of the salt since they are used similarly in the formulation. With regard to the ratios recited by the claims, Higo does not disclose such ratios. Chono et al discloses a matrix-type patch comprising an organic acid salt and a basic drug in a specific ratio (col. 2, lin. 5 – 18). It would be within the level of skill

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in the art to substitute ratios of Chono and apply them to the components of Higo since the compositions are similar. A skilled artisan would have been motivated to substitute the concentrations and ratios of the prior art in order to optimize the effectiveness of the transdermal formulation.

Also with regard to the ratios and concentrations in general, it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to one of ordinary skill in the art to follow the suggestions of the Higo and Chono in order to maximize the delivery of the basic drug, while reducing the crystallization, stabilizing the drug and improving the solubility of the drug. These features would improve the delivery of the basic drug. It would have been obvious to a skilled artisan follow these suggestions with an expected result of a matrix patch comprising basic drug useful for the transdermal delivery of drugs.

Response to Arguments

6. Applicant's arguments, see Amendment, filed 4/15/03, with respect to the rejection(s) of claim(s) 1-26 under 35 USC 102 and 103 have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Higo et al (WO 96/16642) and Chono et al (WO 97/42952).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
July 7, 2003

THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
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